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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,619	04/15/2004	Johannes J. Platteeuw	SYN-0044	6264

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EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
11/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,619	PLATTEEUW ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7-9 and 11-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7-9 and 11-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the Appeal Brief filed on 08/20/08, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 7-9, 11-13 and 18-37 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Disintegrant such as low substituted hydroxypropyl cellulose (L-HPC), is critical or essential to the practice of the invention, but not included in the claims is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). While all of the examples in the specification require the use of L-HPC in order to obtain a quick disintegration time, the present independent claim 1 does not recite any use of a disintegrant, let alone the use of L-HPC as a disintegrant. Applicant's attention is called to the teaching in Kachrimanis et al. (Tensile Strength and Disintegration of Tableted Silicified Microcrystalline Cellulose: Influences of Interparticle Bonding), which shows that silicified microcrystalline cellulose such as Prosolv® decreases disintegration time of the tablet (abstract; and page 1495). Accordingly, in view of the teachings of the present specification and that of Kachrimanis, in order to arrive at the claimed disintegration time, it appears that an essential subject matter is missing from the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 5, 7-9, 14-23, 25, 28-31 and rejected under 35 U.S.C. 102(e) as being anticipated by Christensen et al. US 6,916,941.

Christensen teaches a tablet composition comprising an antidepressant as an active agent, about 80% filler, lubricant, and 3.6% disintegrant (column 5, lines 1-45; and example 2). Filler includes ProSolv SMCC90 (silicified microcrystalline cellulose) (example 2; and claim 39). Disintegrant includes low substituted hydroxypropyl cellulose (ID).

Christensen does not explicitly teach the claimed properties, such as disintegration time, tablet hardness, and tablet friability. However, the burden is shifted to applicant to show that the tablet of Christensen does not have the claimed properties. This is because Christensen teaches a tablet dosage form comprising silicified microcrystalline cellulose in the claimed amount. Further, applicant's attention is called to the teaching of Christensen for the use of disintegrant in the claimed amount.

Claims 1, 5, 7, 8, 11-13, 18-21, 23, 25, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherwood et al. US 5,585,115.

Sherwood teaches a tablet comprising active agent, and about 70% silicified microcrystalline cellulose (examples 10-12). Active agent includes acetaminophen (examples 10-12). The silicified microcrystalline cellulose is a coprocessed microcrystalline cellulose with 5% w/w silicon dioxide (column 5, lines 1-15; and examples 10-12). Sherwood also teaches the claimed average particle of the silicified microcrystalline cellulose (column 11, lines 1-5; and example 1).

It is noted that Sherwood does not explicitly teach claimed properties, such as disintegration time, tablet hardness, and tablet friability. However, when the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Therefore, the burden is shifted to applicant to show that the tablet of Sherwood does not exhibit the claimed properties. This is because Sherwood meets all of the claimed limitations, namely, Sherwood teaches the claimed silicified microcrystalline cellulose in the claimed amount to obtain tablet useful in pharmaceutical art. Further, Sherwood teaches that the obtained tablet possesses excellent disintegration time (column 4, lines 64-66).

Claims 1, 5, 7-9, 11-15, 17-23, 25, 30, 31 and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Frontanes et al. US 6,399,101.

Frontanes teaches a tablet dosage form comprising active agent, from about 90% to about 99% of silicified microcrystalline cellulose matrix, lubricant, and disintegrant (column 5, lines 42-48; column 6, lines 20-53; and examples). Frontanes

further teaches the claimed mean particle size of the silicified microcrystalline cellulose in the region of 90 μm (column 5, lines 11-40).

Frontanes does not explicitly teach the claimed properties, such as disintegration time, tablet hardness, and tablet friability. However, the burden is shifted to applicant to show that the tablet of Frontanes does not have the claimed properties. This is because Frontanes teaches a tablet dosage form comprising silicified microcrystalline cellulose in the claimed amount. Further, applicant's attention is called to the teaching of Frontanes for the use of disintegrant in the claimed amount.

Claim Rejections - 35 USC § 103

Claims 1, 5, 7-9 and 11-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. US 6,328,994, in view of Sherwood et al. or Frontanes et al. or Christensen et al., and Staniforth US 6,660,303.

Shimizu teaches an orally disintegrable tablet comprising 25-40% fine granule of active material, 3-50% crystalline cellulose, 3-50% low-substituted hydroxypropyl cellulose, and other excipients (disintegrant) (column 5, lines 10-13; column 10, lines 13-39; and column 11, lines 34-42). Active material includes omeprazole, and is coated with an enteric polymer (column 5, lines 14-24). Crystalline cellulose includes microcrystalline cellulose (MCC) (column 10, lines 13-24). Shimizu also teaches the tablet exhibits hardness of about 1-20 kg, and an oral disintegration time of about 30 second or less (column 12, lines 42-51).

Shimizu does not teach the use of the claimed microcrystalline cellulose.

Sherwood teaches a tablet comprising active agent, and about 70% silicified microcrystalline cellulose (examples 10-12). The silicified microcrystalline cellulose is a coprocessed microcrystalline cellulose with 5% w/w silicon dioxide (column 5, lines 1-15; and examples 10-12). Sherwood also teaches the claimed average particle of the silicified microcrystalline cellulose (column 11, lines 1-5; and example 1).

Frontanes teaches a tablet dosage form comprising active agent, from about 90% to about 99% of silicified microcrystalline cellulose matrix, lubricant, and disintegrant (column 5, lines 42-48; column 6, lines 20-53; and examples). Frontanes further teaches the claimed mean particle size of the silicified microcrystalline cellulose in the region of 90 μm (column 5, lines 11-40).

Christensen teaches a tablet composition comprising an antidepressant as an active agent, about 80% filler, lubricant, and 3.6% disintegrant (column 5, lines 1-45; and example 2). Filler includes ProSolv SMCC90 (silicified microcrystalline cellulose) (example 2; and claim 39). Disintegrant includes low substituted hydroxypropyl cellulose (ID).

Thus, it would have been obvious to one of ordinary skill in the art to modify the oral dosage form of Shimizu using the silicified MCC in view of the teachings of Sherwood or Frontanes or Christensen to obtain the claimed invention. This is because Sherwood, Frontanes and Christensen teach the use of silicified MCC in tablet composition is well known in the art, because Shimizu teaches the desirability of obtaining a direct compressed tablet that is useful for orally disintegrable administration,

and because Staniforth teaches the advantageous results in the use of silicified microcrystalline cellulose over microcrystalline cellulose (column 3, lines 1-35). This is because Staniforth suggests using silicified microcrystalline cellulose in place of microcrystalline cellulose to overcome tableting problems known in the art.

Response to Arguments

Applicant's arguments filed 08/01/08 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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